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10/005,685	11/07/2001	Kurt E. Petersen	22660-0019 DIV 2	1753

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William Schmonsees  
Heller Ehrman White & McAuliffe  
275 Middlefield Road  
Menlo Park, CA 94025-3506

EXAMINER

BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
1744	3

DATE MAILED: 04/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application N .</b> 10/005,685	<b>Applicant(s)</b> PETERSEN ET AL.
	<b>Examiner</b> William H. Beisner	<b>Art Unit</b> 1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.

- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.

- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on \_\_\_\_.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-53 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_ is/are allowed.

6) Claim(s) 1-8, 14-26, 32-46, 52 and 53 is/are rejected.

7) Claim(s) 9-13, 27-31 and 47-51 is/are objected to.

8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 07 November 2001 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1 and 2</u> .	6) <input type="checkbox"/> Other: ____.

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statements filed 07 Nov. 2001 and 22 Feb. 2002 has been considered and made of record.

### ***Oath/Declaration***

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the mailing or post office address of each inventor. A mailing or post office address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing or post office address should include the ZIP Code designation. The mailing or post office address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

The instant declaration only provides the RESIDENCE of each inventor. There is nothing in the declaration to indicate that the residence is also the inventor's post office address.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 40-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1744

In claims 40-42, recitation of "an aspect ratio of at least 2:1" is indefinite because it is not clear what the ratio is with respect to, that is, width to height, surface area to height, surface area to width, etc.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

6. Claim 18 is rejected under 35 U.S.C. 102(e) as being anticipated by Nelson et al.(US 5,770,029).

The reference of Nelson et al. discloses a cartridge (50) and method of use which includes a sample port (66); a sample flow path (66-62); a flow-through component (62); a waste chamber (63); an elution flow path (57-62-55); and flow controller (58-61) for directing the flow of liquid within the cartridge. The device includes a reaction chamber (65).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1744

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1, 2, 6, 7 and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al.(US 5,770,029).

The reference of Nelson has been discussed above.

With respect to the volumes of sample relative to the volume of the capture chamber, the reference of Nelson et al. discloses that the enrichment channel serves to place the analyte of interest into a smaller volume than the initial sample volume, i.e. analyte concentrator (See

column 4, lines 2-4). As a result, the specific volume of the sample employed would have been merely an obvious matter in design choice based on considerations such as the specifics of the analysis to be performed and/or the source of the sample to be analyzed. Note the reference of Nelson et al. discloses a chamber volume of 1pl to 1ul (See column 4, line 16) and sample volume of 100ul (See Example 1).

11. Claims 3, 4, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al.(US 5,770,029) in view of Brunner et al.(US 5,777,141).

The reference of Nelson et al. has been discussed above.

Claims 3, 4, 19 and 20 differ by reciting the use of a heater in the device to improve elution efficiency.

The reference of Brunner et al. discloses that it is well known in the art to control the temperature and/or pressure within a separation column so as to control elution conditions (See column 7, line 1 to line 24).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the separation chamber of the primary reference with a heater for the known and expected result of improving the separation/elution conditions within the separation chamber.

12. Claims 3, 4, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al.(US 5,770.029) in view of Woodward et al.(US 5,693,785) and Northrup et al.(US 5,639,423).

The reference of Nelson et al. has been discussed above.

The above claims differ by reciting the use of a heater in combination with the capture chamber.

The reference of Woodward et al. discloses that it is known in the art to enhance the elution of a captured analyte from a separation column using heat (See the abstract).

The reference of Northrup et al. discloses that it is known in the art to incorporate a heater device in a microchip analysis device (See column 4, lines 49-67).

In view of these teachings, it would have been obvious to provide the chamber of the modified primary reference with a heater structure for the known and expected result of enhancing the elution of the captured analyte from the capture zone as is recognized in the reference of Woodward et al.

13. Claims 8, 14-17, 26, 32-37, 43-47, 52 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al.(US 5,770,029) in view of Wilding et al.(US 5,726,026 or 5,928,880).

The reference of Nelson et al. has been discussed above.

The claims differ by reciting that the device includes a lysing chamber and associated components for releasing nucleic acid from cell samples.

The reference of Wilding et al. discloses that it is known in the art to provide a microchip device with cell lysing components (See the entire disclosure).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the device of Nelson et al. with the additional lysing components for the known and expected result of providing a means recognized in the art to providing a nucleic acid sample

while eliminating the need for sample treatment prior to introduction of the sample into the cartridge device.

With respect to the claimed reagents and reaction chambers and analysis chambers for nucleic acid, the reference of Wilding et al. also discloses these features for detection of nucleic acid samples (See Figures 11A and 11B).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to modify the system of the primary reference with reagent chamber, reaction chamber, detection chambers, etc. for the known and expected result of providing a device which is capable of extracting and detecting nucleic acid samples as is suggested by the prior art references.

14. Claims 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al.(US 5,770,029) in view of Wilding et al.(US 5,726,026 or 5,928,880) and Brunner et al.(US 5,777,141).

The combination of the references of Nelson et al. and Wilding et al. has been discussed above.

Claims 38 and 39 differ by reciting the use of a heater in the device to improve elution efficiency.

The reference of Brunner et al. discloses that it is well known in the art to control the temperature and/or pressure within a separation column so as to control elution conditions (See column 7, line 1 to line 24).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the separation chamber of the primary reference with a heater for the known and expected result of improving the separation/elution conditions within the separation chamber.

15. Claims 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al.(US 5,770,029) in view of Wilding et al.(US 5,726,026 or 5,928,880), Woodward et al.(US 5,693,785) and Northrup et al.(US 5,639,423).

The combination of the references of Nelson et al. and Wilding et al. has been discussed above.

The above claims differ by reciting the use of a heater in combination with the capture chamber.

The reference of Woodward et al. discloses that it is known in the art to enhance the elution of a captured analyte from a separation column using heat (See the abstract).

The reference of Northrup et al. discloses that it is known in the art to incorporate a heater device in a microchip analysis device (See column 4, lines 49-67).

In view of these teachings, it would have been obvious to provide the chamber of the modified primary reference with a heater structure for the known and expected result of enhancing the elution of the captured analyte from the capture zone as is recognized in the reference of Woodward et al.

16. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al.(US 5,770,029) in view of Wilding et al.(US 5,726,026 or 5,928,880), Hansmann et al.(US 5,707,799) and Mochida (US 5,147,607).

The combination of the references of Nelson et al. and Wilding et al. has been discussed above.

While the reference of Nelson et al. discloses a multitude of binding structures (See column 4, lines 24 to column 5, line 38) which can be employed in the chamber to capture a desired element of the sample liquid, the reference is silent as to the use of an array of structures extending into the chamber with an aspect ratio of at least 2:1.

The reference of Hansmann et al. discloses that it is known in the art to provide an array of pillar structures in a flow device for capturing a desired analyte in a sample fluid.

In view of this teaching, it would have been obvious to one of ordinary skill in the art based merely on the particular application in which the device of Nelson et al. is to be employed to employ an array of structures as disclosed by the reference of Hansmann et al. for the known and expected result of providing a means recognized in the art for contacting a fluid sample with a capturing surface wherein the array of pillar structures provides a large surface area for contacting.

With respect to the claimed aspect ratio, the reference of Mochida discloses an analyte capture device which includes an array of pillar structures (See Figures 19a-19c) wherein the pillars are at least twice as tall than wide.(See column 17, lines 4-13).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to determine the optimum

number, shape, size and/or dimensions of the array of pillars based on considerations such as the size of the chamber and/or the material to be captured in the chamber on the pillars while maintaining the efficiency of the separation system.

17. Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al.(US 5,770,029) in view of Wilding et al.(US 5,726,026 or 5,928,880), Hansmann et al.(US 5,707,799), Mochida (US 5,147,607) and Brunner et al.(US 5,777,141).

The combination of the references of Nelson et al., Wilding et al., Hansmann et al. and Mochida has been discussed above.

Claims 41 and 42 differ by reciting the use of a heater in the device to improve elution efficiency.

The reference of Brunner et al. discloses that it is well known in the art to control the temperature and/or pressure within a separation column so as to control elution conditions (See column 7, line 1 to line 24).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the separation chamber of the primary reference with a heater for the known and expected result of improving the separation/elution conditions within the separation chamber.

18. Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al.(US 5,770,029) in view of Wilding et al.(US 5,726,026 or 5,928,880), Hansmann et al.(US 5,707,799), Mochida (US 5,147,607) and Woodward et al.(US 5,693,785) and Northrup et al.(US 5,639,423).

The combination of the references of Nelson et al., Wilding et al., Hansmann et al. and Mochida has been discussed above.

The above claims differ by reciting the use of a heater in combination with the capture chamber.

The reference of Woodward et al. discloses that it is known in the art to enhance the elution of a captured analyte from a separation column using heat (See the abstract).

The reference of Northrup et al. discloses that it is known in the art to incorporate a heater device in a microchip analysis device (See column 4, lines 49-67).

In view of these teachings, it would have been obvious to provide the chamber of the modified primary reference with a heater structure for the known and expected result of enhancing the elution of the captured analyte from the capture zone as is recognized in the reference of Woodward et al.

### ***Double Patenting***

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20. Claims 1-7 and 18-25 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-22 of copending Application No. 09/513,443 in view of Hansmann et al.(US 5,707,799) and Mochida (US 5,147,607). The above claims differ by not being limited to the 2:1 aspect ratio of the claims of application 09/513,443. However, the references of Hansmann et al. and Mochida as previously discussed above teach that this difference is obvious for reasons already of record.

This is a provisional obviousness-type double patenting rejection.

***Allowable Subject Matter***

21. Claims 9-13, 27-31 and 47-51 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

22. The following is a statement of reasons for the indication of allowable subject matter:  
While the prior art of record discloses a method of using a microdevice to extract and purify a sample analyte which includes a lysing region or step, the prior art of record fails to teach or fairly suggest the use of a separate lysing chamber which includes a solid phase for binding the sample components and transferring ultrasonic energy to the captured components so as to lyse the sample components in the lysing chamber.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Warden can be reached on 703-308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



William H. Beisner  
Primary Examiner  
Art Unit 1744

WHB  
April 22, 2002